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REVIEW

Fixation principles in metaphyseal bone—a patent based review

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Abstract Osteoporotic changes start in cancellous bone due to the underlying pathophysiology. Consequently, the metaphyses are at a higher risk of "osteoporotic" fracture than the diaphysis. Furthermore, implant purchase to fix these fractures is also affected by the poor bone quality. In general, researchers and developers have worked on three different approaches to address the problem of fractures to osteoporotic bone: adapted anchoring techniques, improved load distribution as well as transfer with angular stable screws, and augmentation techniques using bone substitutes. A patent-based review was performed to evaluate which ideas were utilized to improve fixation in osteoporotic, metaphyseal bone, especially in the proximal femur, and to analyze whether the concept had entered clinical use. Anchoring devices that are either extramedullary or intramedullary have a long clinical history. However, demanding surgical techniques and complications, especially in poor quality bone, are justification that such implants and their corresponding surgical techniques need to be improved upon. Expanding elements have been evaluated in the laboratory. The results are promising and the potential of this approach has yet to be fully exploited in the clinics. Internal fixators with angular stable screws open the door for many new anchorage ideas and have great potential for further optimization of load distribution and transfer. Augmentation techniques may improve anchorage in osteoporotic bone. However, the properties of bone substitute materials will need to be modified and improved upon in order to meet the demanding requirements. If we summarise the development process and the clinical use of implants to date, we have to clearly state that more factors than simply biomechanical advantage will determine the clinical success of a new fixation principle or a new implant. Instead, fracture treatment of patients with osteoporosis really needs an interdisciplinary approach!

Keywords Fracture · Implant · Implant anchorage · Implant failure · Osteoporosis · Patent

Introduction

The method of fixation for metaphyseal fractures in osteoporotic bone is important for two reasons. Firstly, cancellous bone is more susceptible to loss of bone mass due to osteoporosis [1–3]; consequently, the metaphyses are at a higher risk of "osteoporotic" fracture than the diaphysis. As a result, there is a high incidence of metaphyseal fractures such as proximal femoral fractures, fractures of the proximal humerus and of the distal radius [4,5]. Secondly, implant purchase in osteoporotic metaphyseal bone is also affected. In the case of a fracture, the poor quality of the trabecular network would therefore require more (adequate) fixation elements. However, the number and size of implants that can be placed, especially in the articular fragment, is often limited.

In general, researchers and developers have worked on three different approaches to address the problem of fractures to osteoporotic bone: adapted anchoring techniques, improved load distribution as well as transfer with angular stable screws, and augmentation techniques using bone substitutes.

In the following text, the authors present a review based upon 21 patents which demonstrates the evolution of different implants that have been either specifically

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designed for application in osteoporotic metaphyseal bone, or which may be adapted for use in osteoporotic metaphyseal bone.

A fourth approach, prosthetic joint replacement, will not be addressed in this review.

Anchoring techniques

The high incidence of fractures of the proximal femur and the often deleterious effect of a fracture to the individual patient has led to the development of numerous implants for this indication. The general search for the optimal fixation principle to treat osteoporotic metaphyseal fractures is exemplified by the progress as well as pitfalls in the methodology to develop specific implants for the proximal femur. This section will look at anchoring techniques in conjunction with extramedullary, intramedullary and expanding fixation elements.

Extramedullary fixation elements

Angle blade plate

The ''blade'' is one of the oldest fixation principles; it provides a broad surface contact area perpendicular to the main loading axis within metaphyseal bone. It is capable of resisting considerable torsion and bending moments.

One of the earliest designs of the angle blade plate is described in the following patent from 1964: mechanism to repair the proximal femur joint [6]. This invention comprises a plate portion and a blade extension. The blade is driven through the femur neck into the joint head. The cross section of the blade has a ''U'' profile. The side walls and base of the blade are ''chisel-like''. Due to this form, minimum bone loss occurs when inserting the blade into the bone (Fig. 1a).

The ''U'' profile described above is an optimum compromise between the minimal amount of bone removal that is necessary for implantation and the maximum stiffness of the implant. The plate portion is fixed to diaphyseal or metaphyseal areas of the long bones. The angle blade plate was originally developed for the stabilization of proximal or distal femur fractures [7]. However, several authors found it beneficial to use the angle blade plate in other metaphyseal regions too [8–11]. Its use has been described, for example, in the treatment of fractures and non-unions in the proximal tibia and proximal humerus. Biomechanical studies have confirmed improved loads to failure of blade plates over conventional screw-plate devices. The use of an angled blade plate device rather than a screw-plate device, e.g. dynamic hip screw (DHS), is recommended, as the bone is impacted by the blade rather than removed by the drilling process required for screw insertion [12]. Additionally the position of the blade can be revised without compromising fixation [13,14].

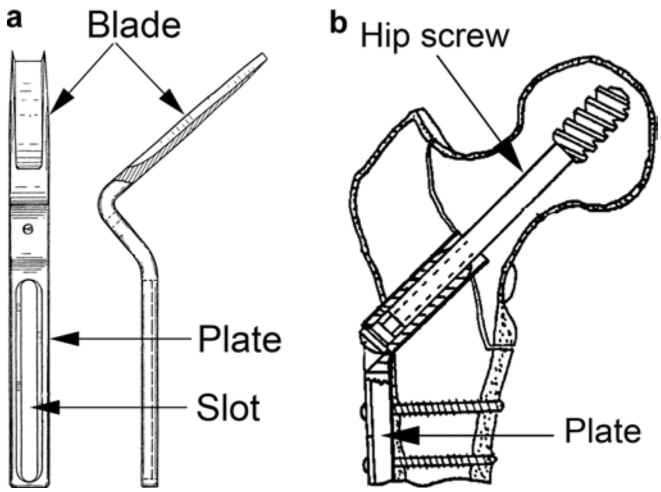

Fig. 1 Angle blade plate with ''U'' shaped blade profile. The slot in the plate allows for height adjustment (**a**). The DHS with a modular screw component in the femoral head, which allows for secondary impaction of the fracture (**b**)

Clinical usage is, however, limited by the demanding surgical technique required to insert these one-piece implants. This has led to a higher complication rate in clinical studies [15,16].

Dynamic hip screw (DHS)

The DHS was developed to overcome the surgical problems of insertion of the blade plate at the proximal femur, and utilizes the same principle as the dynamic condylar screw (DCS) at the distal femur [17–19]. In both cases, a large-diameter screw provides the anchorage within the articular bone fragments, i.e. in the femoral head or condylus (Fig. 1b). The key feature of the DHS is the dynamic slide of the screw, which allows for secondary impaction of the fracture along the axis of the screw. The DHS is the implant of choice for stable pertrochanteric fractures. It consists of a plate with a guide barrel attached.

Several factors determine the performance of these devices. Accurate placement of the screw in the femoral head appears to be a critical factor. Placement in the superior quadrant may lead to failure by pull-out, particularly in osteoporotic bone. Cut-out was described in several clinical studies [20,21]. However, if the DHS is inserted correctly, the failure rate of fixation is universally observed to be under 5%, even in patients with osteoporosis [22]. The tip–apex distance (TAD) has been devised by Baumgaertner and Solberg [23] to give the surgeon a guideline for accurate screw placement. The TAD is calculated by summing the distances from the screw tip to the surface of the femoral head in both the anteroposterior and the lateral plane. A TAD under 25 mm is recommended, as no screw cut-out occurred in a retrospective series when this had been achieved.

The following two patents, which span almost a decade, highlight important technical aspects of the DHS concept.

Osteosynthesis anchoring screw (1991) [24]. The profiles of hip screw threads are similar to conventional bone screws where the thread tips are sharp and hence cut into the bone (Fig. 2). Physiological loading of the femur head comprises mainly compressive forces in this indication. These forces applied to osteoporotic femur heads can lead to penetration of the implant into the joint. This invention describes an anchoring screw that has optimised thread geometry whereby the thread tips are blunt, resulting in a geometry optimised for physiological load bearing.

Device for attaching fractured hip joint heads (1998) [25]. This invention comprises a bone plate, which is attachable to the femur, a sleeve that extends at an angle from the bone plate and an anchor bolt which can be inserted into the sleeve. The shaft of the anchor bolt and the inside of the sleeve have corresponding axial grooves that prevent rotation while allowing axial movement.

The trochanteric stabilizing plate (TSP)

The trochanteric stabilizing plate (TSP) is intended for unstable fracture patterns. It supplements the standard sliding hip screw construct by buttressing the greater trochanter and preventing lateral displacement.

In a prospective clinical trial, Babst et al. found that the TSP prevented excessive fracture impaction and consecutive limb shortening in 90% of patients [26].

Intramedullary nails and fixation elements

Due to theoretical biomechanical advantages, intramedullary devices were especially developed for fixation of pertrochanteric femoral fractures: the intramedullary nail is located more medially and therefore has a shorter lever arm than previous sideplate constructs. Furthermore, intramedullary fixation of proximal humerus fractures and distal femoral fractures is a minimally invasive technique that preserves the blood supply of the periosteum and soft tissue while simultaneously providing strong fixation. IM fixation is especially recommended for fracture treatment in osteoporotic bone because its central location distributes loads uniformly. Since the osteoporotic bone is already in a weakened state, this distribution is very beneficial [27].

Locked cross nails and screws

The following two patents from 1969 and 1990, respectively, describe intramedullary devices that utilize locked cross nails or femur neck screws.

Intramedullary rod and cross nail assembly for treating femur fractures (1969) [28]. An intramedullary rod which conforms generally in shape and dimensions to those of the medullary canal, including a cross nail extending through the rod and having its ends positioned to be engaged in adjoining trochanteric portions of the femur, and a set screw in the rod for locking the cross nail in an operative anchoring position (Fig. 3). One objective of the invention is to produce effective fixation or immobilization of the bone fragments or parts and thereby to facilitate reduction of fractures in the upper third of the sub-trochanteric portion of the femur shaft.

An osteosynthesis aid to support subtrochanteric fractures (1990) [29] comprises a locking femur nail and a femur neck screw, incorporating a self-cutting thread. A locking pin is described which may be placed in the locking nail to prevent rotation, while allowing axial movement of the femur neck screw. This invention, however, would not prevent rotation of the bone fragments.

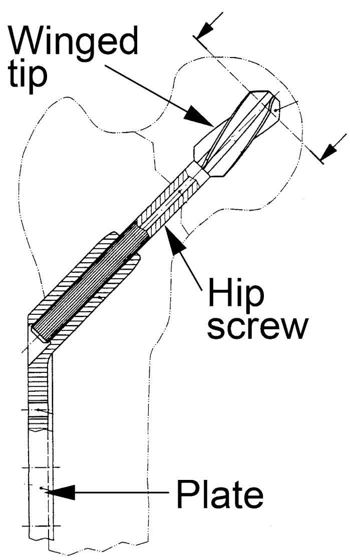

Fig. 2 Device for attaching fractured hip joint heads incorporating a multi-pitch thread at the tip of the head component. Rotation of the femur head is prevented due to the steep spiral angle of the "wings"

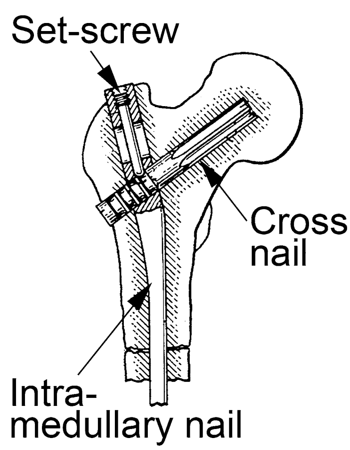

Fig. 3 Intramedullary rod and cross nail with a star-shaped profile in the femoral head

Spiral blade plate

Before the introduction of the spiral blade, the use of intramedullary nailing in proximal humerus fractures and distal femoral fractures in osteoporotic patients did not provide ideal fixation [30]. The principle of the spiral blade includes an increase in the load-bearing surface, featuring a projected surface area 75% greater than previous locking screws. This increase in the load-bearing surface should lower osseous stress at the bone–metal interface [12] (Fig. 4a).

The evolution of the spiral blade plate is demonstrated in the following three patents dating from 1962 up to 1996.

Fixation device for fractured femur (1962) [31]. A primary objective of the invention is to provide a femoral device which may be inserted through a relatively narrow slot extending longitudinally to the subtrochanteric shaft of the femur, the device being constituted by a structural component formed on a helix, which is an integral part of the supporting plate. A further objective is to provide a comparatively large supporting area for sustaining loads imposed upon the femoral head (Fig. 4b).

Osteosynthetic assembly with twist fixation plate (1991) [32]. Described here is an intramedullary nail for insertion into the medulla of a femur and a fixation plate with a twisted blade for insertion into the femur head. The blade is twisted helically about 90° and is able to transmit heavy loads both to the bone and to the intramedullary nail. The assembly may also be used to treat brittle bone, such as is caused by osteoporosis.

Device for holding broken bones in a fixed position (1996) [33]. A device for fixing fractures in the region of joints, having a blade plate and a side plate intended for fixation to the shaft of the long bone. The blade plate and the side plate can be connected to each other at a selectable angle in the range of 90–150°.

Studies suggest improved mechanical properties of the spiral blade plate when compared with traditional locking bolts [34]. Clinical reports of implant failure have, however, given rise to concern about the widespread clinical use of the spiral blade plate [35–38]. Despite this, the latest implant generation seems to be experiencing a renaissance.

The double-T-plate

Another approach to optimize the implant-bone interface was the utilization of a double-T-blade profile by Friedl and colleagues [39,40] (Fig. 5). Good clinical results in elderly patients were reported by the inventor and by Schwammle et al. [41]. The double-T-blade was used to achieve high primary stability of the fracture fixation. Although the biomechanical principle seems logical, the implant has not gained widespread acceptance up to now.

Up to this point we have mainly discussed load-carrying devices such as the angle blade or spiral blade plates. A relatively new and different concept is to improve the purchase of the implant in the bone using expandable elements.

Osteosynthesis using expandable elements

Expandable elements have been evaluated in biomechanical studies and their effectiveness has been demonstrated [42].

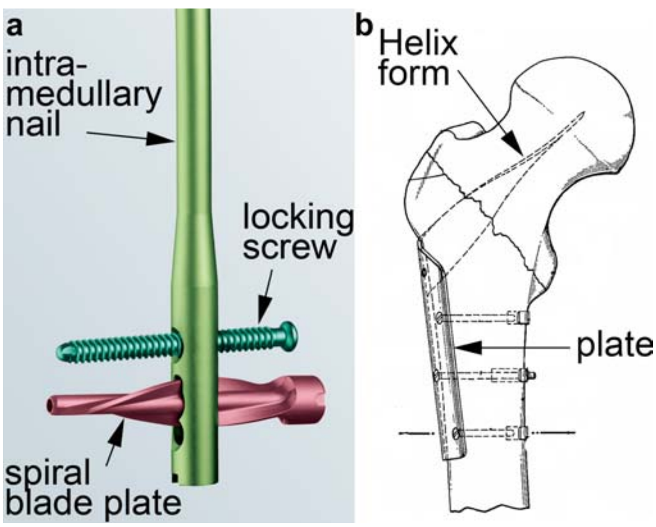

Fig. 4 Replacement of conventional screw by a spiral blade plate in combination with an intramedullary nail. The implant provides the best possible contact surface for fixed angle locking in osteoporotic bone (**a**). A device for the proximal femur which features a plate with an integral structural component formed on a helix (**b**)

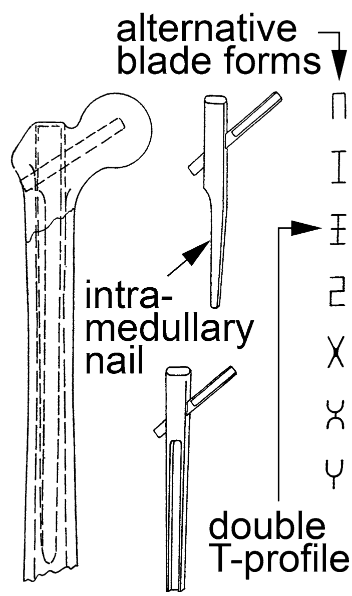

Fig. 5 Intramedullary rod with alternative blade forms for the proximal femur including the "double-T" profile

Rivets and plugs

One idea is to adapt the concept of the rivet as used in metal work. For example, Steiger and co-inventors have patented a device for fixing surgical implants (2003) [43] (Fig. 6). The principle of the rivet has proven to be effective where anchorage of screws may be difficult [44].

A further example is that of Frei and Hehli, who have patented an osteosynthetic anchoring element (2001) [45]. This invention is characterized by expanding radial arms, which anchor into the bone (Fig. 7).

Plate osteosynthesis utilizing anchoring arms

Novel inventions that involve plate designs with features, which eliminate the need for fixation screws, have been created. One such idea is described in the patent of Ulrich Mennen (Fig. 8).

Internal fixation device for bone fractures [46]. According to the invention, an internal fixation device for a bone fracture is provided. The device is made up of a metal plate having fastening arms formed on at least two edges of the plate, which can be secured to a bone fracture site by deforming and penetrating directly into the bone thereby bridging a bone fracture.

The "Mennen plate" has been used for the treatment of periprosthetic femoral fractures. Although the plate offered some benefits for this indication, several surgeons have described pitfalls such as non-unions and implant failure using this implant type [47–52].

Improved load distribution and transfer with angular stable screws

Locked internal fixators

Conventional plate designs rely upon direct contact and friction between the plate and the bone as a result of the axial preload of the screws, which presses the plate against the bone.

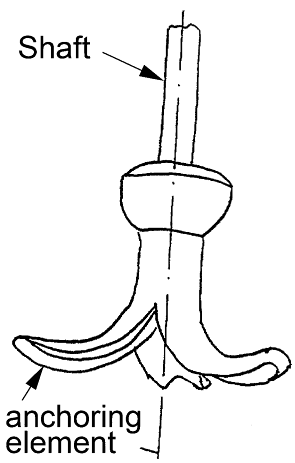

Fig. 6 The bone rivet, demonstrating anchoring elements, which engage into the bone. The principal of this design is similar to rivets used in metalwork

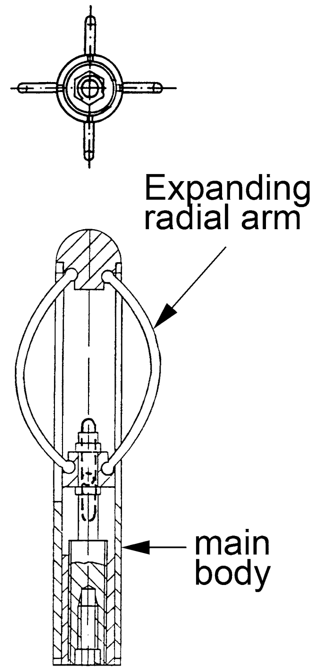

Fig. 7 An anchoring device featuring expanding radial arms for engagement into the bone

Advances in fracture fixation include the advent of locked internal fixators. The interlocking of screws within plates allowed minimization of the bone to implant contact area that was previously identified as deleterious to the blood supply [53]. The principle of interlocked screws has removed the need for axial preloading of the screws, as the internal fixator no longer relies on friction and intimate contact between plate and bone for stability. Instead, the bone is fixed at each point along the length of the fixator. This provides for a very stable construct, as there is no toggle at the plate-screw interface. In addition, locking has allowed elevated applications, which means that pre-shaped implants can be used.

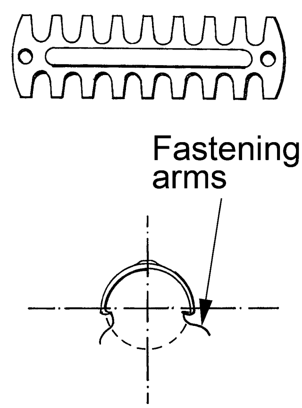

Fig. 8 The Mennen plate with fastening arms, which deform and penetrate into the bone

The screw nut

One of the first examples of this concept is described in the patent of Mast: a screw nut for plate osteosynthesis (1993) [54] which fixes the screw to the plate and acts as a distance holder for reducing the contacting area between bone plate and bone (Fig. 9a). The invention can be used with any type of bone plate and bone screw and at any selected position (hole) of the plate.

Biomechanical testing has demonstrated that the screw nut enhances fixation strength, especially in poor bone stock [55].

The point contact fixator (PC-Fix)

The PC-Fix was one of the first implants that applied this new concept to patients (Fig. 9b). The main features are highlighted below.

Bone plate with conical holes (1994) [56]. According to this invention, the plate is applied to the bone by means of short screws designed with a conical head, which upon insertion lock safely in the conical hole of the plate. The locking between the plate and screws prevents tilting of the screws within the cortex. Loads between the bone and the plate are transferred directly though the screws, which now act as pegs under shear rather than anchors under tension. The plate undersurface is shaped so as to permit only point contact to the bone at very small areas (Fig. 9b).

Early experience with the use of PC-Fix for forearm fractures has proven the efficacy of locked fixators, especially in the setting of osteoporotic bone [12] (Fig. 10).

The less invasive stabilization system (LISS)

The PC-Fix is no longer in clinical use. It has been superseded by the LISS, which is described in the following patent: bone plate (2001) [57]. Similar to the PC-Fix, the bone screws to anchor the bone plate have a conical head. However, the surface of the screw head has a thread or spiral structures. The plate holes are fitted with a thread, which matches that of the screw head.

The LISS is indicated for stabilization of fractures of the distal femur and the proximal tibia, and is applied via a minimally invasive surgical procedure. The plate lies beneath the deep fascia and muscle but outside the periosteum and is anatomically pre-shaped. It preserves blood circulation because the plate is inserted through a small incision at the epiphyseal level and no excessive soft tissue dissection is needed [58,59]. Clinical results have shown that LISS is beneficial for osteoporotic bones and periprosthetic fractures [60,61].

One drawback of the LISS as an internal fixator is that it cannot be used as a reduction tool. The fracture must be reduced and held in traction prior to plate application.

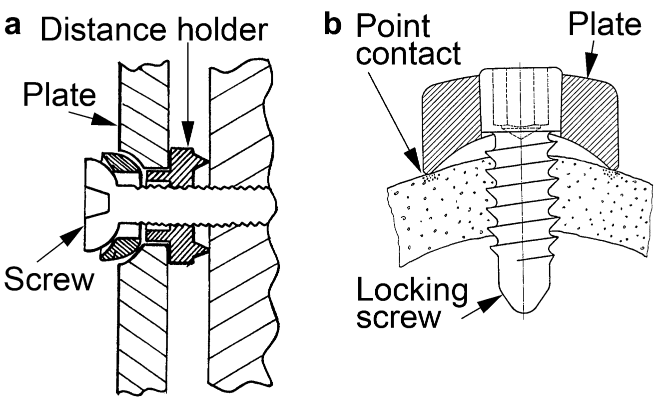

Fig. 9 The "Schuhli" screw nut, which acts as a distance holder for reducing the contacting area between bone plate and the bone (**a**). The PC-Fix incorporating short locking screws and point contact of the plate to the bone (**b**)

The locking compression plate (LCP)

The most recent development in the field of locked internal fixators is the LCP. The advantages of this system are that improved fixation using locked compression is combined with giving the surgeon the option to use the fixator as a reduction tool. However, this system requires demanding teaching due to the complexity of application. The key features of the LCP are described below.

Bone plate (2000) [62]. This novel bone plate can serve as a dynamic compression plate (DCP) and as a so-called internal fixator at the same time, as effectively as if the two elements were separate (Fig. 11). The shape of the conical thread is identical to the LISS described above. The locking head screw is captured in the threaded part of the threaded hole through more than 200° when using the LCP as an internal fixator.

The last approach discussed in this section is to substitute the conically shaped screw head and plate hole, with a screw head and plate hole having a spherical form. The invention of Wolter facilitates placement of the screw by the surgeon at an angle of choice.

Fixation system for bone (1999) [63]. A bone plate is applied to the bone by means of bone screws. The head of the bone screw and the plate holes have a thread. The head of the screw has a spherical form, which allows the screw to be fixed in the plate hole at various angles. The pitch of the screw thread on the screw head is smaller than the pitch of the thread on the screw shaft.

Unlike the locked internal fixators described earlier, the plate in this invention ends up being pressed onto the bone surface as a result of the (two) different thread pitches on the screw head and shaft [64].

Augmentation techniques using bone substitutes to improve anchorage

Despite the very successful developments described earlier in this article, failed fracture fixation remains an

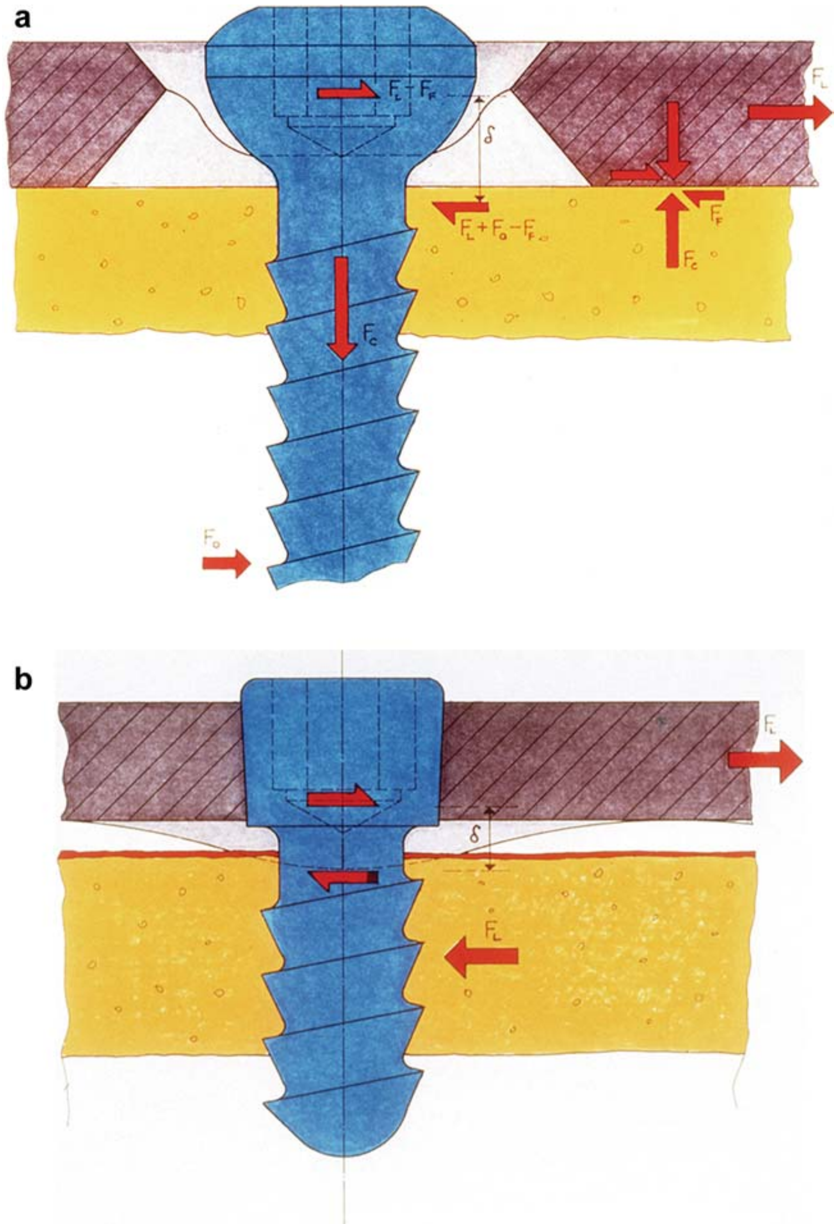

Fig. 10 Load distribution in a conventional plate-screw construct (**a**) and in the PC-Fix (**b**)

important clinical problem especially with osteoporotic bones. Although the quality of fracture reduction and the choice and placement of an internal fixation device are controlled by the surgeon, bone quality is not.

Researchers have investigated different ways to address this problem. In one study, osteotomies in osteoporotic human cadaveric humeri were fixed with metal plates and screws in three experimental groups. The influence of using either poly (L-lactide) or methylmethacrylate augmentation devices were compared to non-augmented fixation. Screw pullout and torsion tests were performed. The investigators concluded that resorbable polymeric medullary augmentation devices could be used to enhance plating of osteoporotic bones [65].

If there is severe osteoporosis, the basic problem is that the rigid metal implant is not adapted to the "soft" osteoporotic bone. Materials for bone augmentation may increase purchase for internal fixation devices in poor bone, assist in stabilizing comminuted fractures, and facilitate load transfer. Different types of materials have been investigated using different techniques as described below to achieve the goal. Despite several reports on successfully improved biomechanical load bearing capacities [66], and despite reports on early clinical application, none of them has so far been adopted for routine clinical use [67–69].

Prophylactic and post-traumatic augmentation techniques

Augmentation of cannulated hardware

The augmentation techniques described in the following patents may prove suitable for application or adaptation

Fig. 11 The PHILOS implant system illustrates the concept of combining the DCP with the locked internal fixator

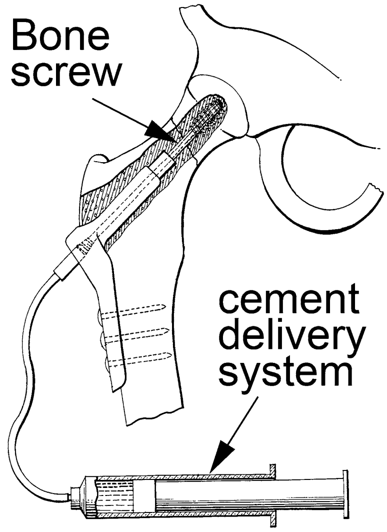

Fig. 12 Hip screw with cement delivery system. Bone cement may be introduced into the increased trabecular spacing in osteoporotic bone

in different anatomical regions of metaphyseal bone. One option is to use bone substitutes in preventive treatment as explained in the recent patent of Margulies and co-inventors.

Method and apparatus for augmentation of the femoral neck (2003) [70]. This invention describes combining an implant and cement for prophylactic and/or preventive use for femoral neck augmentation. A hole is drilled into the femoral neck. The hole is filled with an uncured filler cement. Loose materials are removed, then an open-ended tube shaped implant having openings in its walls is inserted into the hole and attached to the bone. Additional filler cement is provided under pressure which flows into spaces in the bone structure via the tube wall openings (Fig. 12). The proposed invention provides a new method of surgical prevention, by performing a minimal and novel surgical procedure before a fracture occurs. In this way, a more invasive and more complicated procedure may be prevented.

Internal fixation in severely osteoporotic, comminuted, unstable intertrochanteric fractures has been augmented by packing cements such as methylmethacrylate around the implant in a rather crude manner. Augat et al. showed that controlled augmentation with bone cement could significantly improve fixation strength, for example, in proximal femoral fractures [71]. Problems exist, however, with putting or placing such cements into the fracture site in cases of non-union. Extreme care must be taken to ensure that the cement is not extruded between the main fracture fragments since otherwise, the foreign body will absolutely prohibit bony union. The essential keystone of this invention is the fenestration between the screw blades so that cement can be injected into the femoral head and away from the fracture site as such, further locking the screw threads into the bone. It is important to note that screw threads (rather than any nail blades) cut out spiral grooves along which a better penetration and a more evenly controlled injection of cement can occur for a more reliable implant–cement–bone fixation (Fig. 13). The use of fenestrated or cannulated screws is illustrated in the following patents from Tronzo (1987) and Reynders and Berger (2001).

Fenestrated hip screw and method of augmented fixation (1987) [72] describes a fenestrated hip screw through which a fixing cement can be introduced into a region of bone where a problem of osteoporosis exists.

Bone screw (2001) [73] teaches the use of a screw with a bore, which reaches the outside in the form of at least one perforation. The advantage of the bone screw is that osteocementum can be introduced into the adjacent bone in such a way that an artificial coaxial cement bed for the thread of the bone screw is formed. The cement bed is only laterally adjacent to the screw such that the screw can be axially advanced even if the osteocementum has hardened.

The final patent in this section describes the application of the augmention material under vacuum. This may prove to be beneficial by allowing optimal filling of the cancellous bone.

Suction drainage bone screw (1995) [74]. In arthroplastic surgery, most implants are implanted in the bony bed using so-called bone cement. This bone cement is usually made of polymethylmethacrylate. However, the

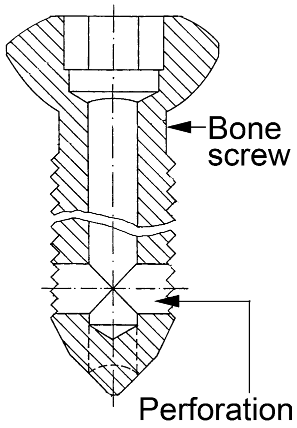

Fig. 13 Bone screw with perforations, which facilitate delivery of the bone cement into the surrounding bone

bone cement can only penetrate into the honeycombs of the bone marrow if they are clean and free of fat marrow and cell compounds. The bone screw of the invention has an axially continuous longitudinal canal or bore in its interior and is adapted to receive a vacuum line in the appropriate manner, preferably in the vicinity of the screw head. Thus it is possible to suck the blood and fat out of the bone canal and the surrounding area around it through the longitudinal canal of the bone screw. The bone screw of the invention renders it possible to fill the canal with bone cement under vacuum. It is absolutely imperative to fill in the cancellous bone with cement in the areas in which it is under load in order to reinforce the framework against deformation.

The use of bone cements as an augmentation material challenges the materials researcher, since the loading in a compound system produces considerable shear forces in the augmentation material. Materials that have been tested to date either in the laboratory or in the clinics do not have adequate shear strength, hence their success has been limited.

Conclusions

Within the past 40 years, osteosynthesis has become a well standardized treatment modality for fractured bones with good success rates. Fracture fixation in osteoporotic bone, however, is still a challenge that may even increase within the next decade due to demographic changes. This is especially true for articular and metaphyseal fractures.

Despite excellent results with prosthetic treatment of hip fractures, this cannot be looked upon as the ultimate solution for all patients and all joints.

Extramedullary or intramedullary anchoring devices have a long clinical history. However, demanding surgical techniques and complications, especially in poor quality bone, are justification that such implants and their corresponding surgical techniques need to be improved upon. Expanding elements have been evaluated in the laboratory. The results are promising and the potential of this approach has yet to be fully exploited in the clinics. Internal fixators with angular stable screws open the door for many new anchorage ideas and have great potential for further optimization of load distribution and transfer. Augmentation techniques may improve anchorage in osteoporotic bone. However, the properties of bone substitute materials will need to be modified and improved upon in order to meet the demanding requirements.

To summarise the development process and the clinical use of implants to date, it should be clearly stated that more factors than just biomechanical advantage will determine the clinical success of a new fixation principle or a new implant. Instead, fracture treatment of patients with osteoporosis really needs an interdisciplinary approach!

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